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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,320	02/13/2001	Bernhard H. van Lengerich	BVL-102A	9819

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Douglas J. Taylor, Esq.
General Mills, Inc.
P.O. Box 1113
Minneapolis, MN 55440

EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/782,320	VAN LENGERICH, BERNHARD H.	
	Examiner	Art Unit	
	LEZAH ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

5a) Of the above claim(s) *94* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *See Continuation Sheet* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 25-31,34,35,37-40,42,46,50,52-59,61,62,64-67,69,70,73,75,79,81-85,91-97,101,103,105 and 108-110.

Continuation of Disposition of Claims: Claims rejected are 25-31,34,35,37-40,42,46,50,52-59,61,62,64-67,69,70,73,75,79,81-85,91-93,95-97,101,103,105 and 108-110.

DETAILED ACTION

Applicants' arguments in the Appeal Brief, filed July 1, 2011, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

In view of the Appeal Brief filed on July 1, 2011, PROSECUTION IS HEREBY REOPENED. New Rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below (see end of action).

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 25, 26, 28, 30, 31, 35, 37-40, 46, 91, 92, 101, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiltz (US 5,449,708) in view of Farquharson et al. (US 4,888,174).

Schiltz discloses starch-based biodegradable polymers. It is a homogeneous mixture of starch, an ethylene acrylic acid co-polymer, and a salt of stearic acid (a fatty acid of instant claim 31, also has a hydrophobic component meeting instant claim 30). An aqueous lubricant material is then added to the mixture. Excess moisture is removed under reduced pressure and a plastic material is extruded (Abstract), meeting the limitation of plasticized matrix. The starch is 20% to 90% by weight of the total composition (col. 4, lines 52-56), meeting instant claims 25 and 39. The starch component is substantially gelatinized before and during its mixture with the copolymer and/or additional polymeric components, meeting the limitation of instant claim 26. The compositions may be formulated into pellets, powders, granules and regrind (col. 11, lines 66-68), meeting instant claim 28. The components are mixed to achieve a homogeneous mixture (col. 4, lines 17-20). Other additives include anti-oxidants (meeting instant claim 46), stabilizers, herbicides, fungicides and fertilizers. The additives may be added in amounts necessary to achieve the desired effect in a manner entirely consistent with the continuous method described herein (col. 7, lines 56-59).

The starch may be obtained from corn, wheat, rice, potato and tapioca (col. 7, lines 65-68). Gelatinization disrupts the starch granules providing access to individual starch molecules (col. 8, lines 14-20). The residual moisture during processing the compositions plasticize the starch (col. 6, lines 56-63), meeting the limitation that the plasticizer comprises water. Polyethylene is further provided as an additional polymeric material (col. 4, lines 21-25).

The reference differs from the instant claims insofar as it does not disclose the amount of additive incorporated into the compositions or the size of the films or pellets.

Farquharson et al. disclose a composition comprising an insecticide and a polymer. The compositions may be formulated into films. The compositions may be incorporated into polymer pellets. The size of the pellet can range in diameter from about 1/16 to about 1/2 inch (1.58 mm to 12.7 mm), meeting instant claims 35, 37 and 40. The film thickness ranges from 0.5 mil to about 4 mil (0.0127 to 6.35 mm) (col. 6, lines 35-50).

The reference differs from the instant claims insofar as it does not disclose the films comprise starch.

It would have been obvious to one of ordinary skill in the art to have made the pellets of Schiltz a size where the diameter ranges from 1/16 to ½ inch motivated by the desire to make pellets a size disclosed by the art as suitable for pellets used in agriculture.

Schiltz discloses temperature ranges up to 135 degrees C (col. 4, lines 4-20) similar to those disclosed by the instant specification up to 160 degrees C and below

the decomposition temperature of starch. Thus it is reasonable to conclude that the starches used by Schiltz are not "substantially dextrinized" or "substantially destuctured".

In regard to the amount of encapsulant, Schiltz discloses the additives may be added in amounts necessary to achieve the desired effect in a manner entirely consistent with the continuous method described herein. Therefore it would have taken no more than the relative skill of one of ordinary skill in the art to have adjusted the amount of additive to obtain the desired effect. It would have been obvious to one of ordinary skill in the art to have used the additives in amount ranging from 1% to 85% motivated by the desire to obtain the desired effect of the additive.

The prior art does not disclose the exact claimed values of about 40% or more and 60% to 95% of at least on matrix material and up to about 10 mm, but does overlap disclosing 20% to 90% starch and a diameter ranging from 1.58 to 12.7 mm: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to one of ordinary skill in the art to have used starch in an amount of 40% or more and made a pellet with a diameter of up to about 10 mm consistent with the In re Peterson decision.

2) Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C.

103(a) as being unpatentable over Loomis et al. (US 5,852,114) in view of Newton et al. (US 4,938,967).

Loomis et al. disclose biodegradable thermoplastic polymer blends comprising a first polymer and a second polymer. The polymers form a homogeneous blend (Abstract). The first polymer includes hydrophobic polymers and may comprise 20% to 80% by weight of the total composition. Polymers also include polyvinyl pyrrolidone meeting instant claims 50 and 79. The second polymer ranges from about 10% to 70% by weight of the total composition and includes polyvinyl acetate copolymers, pectins, polysaccharides, starch, cellulose and alginates. A starch component is also incorporated into the composition to impart further desirable physical properties and characteristics (col. 4, lines 63-67). The starch component includes native or granular starch, chemically modified starch, gelatinized starch and destructurized starch and combinations thereof, meeting the limitations of instant claim 54, 108 and 109. Native and granular starch is selected from potatoes, rice, tapioca, corn, rye, oats, wheat and combination thereof. The starch component may comprise 5% to about 50% (col. 8, lines 36-52). Optional components, which may also be added to the compositions of the present invention to impart further desirable physical properties and characteristics, may be selected from the group consisting of extenders; fillers; lubricants; mold-release agents; ultraviolet stabilizers; coloring agents; anti-oxidants (instant claims 46 and 75) and combinations thereof. Lubricants include stearates and lecithin (instant 30 and 31). Stabilizers include antimicrobial agents. Extenders include soybean proteins and gelatin (col. 9, line 54 to col. 10, line 46), meeting the limitation of instant claims 52, 54, 83, 108

and 109. The compositions may be used for the controlled delivery of pharmaceuticals or agricultural chemicals (col. 13, lines 1-5). The compositions are formulated into granule, pellets or powders (col. 11, lines 27-35), meeting instant claims 28 and 55. The reference discloses water is removed and therefore water is present meeting the limitation of the plasticizer comprising water.

The reference differs from the instant claims insofar as it does not disclose the dimensions of the granules, pellets or powders; or the amount of optional components that may be added to the compositions.

Newton et al. disclose pharmaceutical compositions. The dosages are preferably capsules that contain one or more units. Density of conventional tablets and pellets is usually about 1.0 to 1.5 g/ml (1000 to 1500 g/liter) (col. 1, lines 11-13), encompassing claim 34. Selection of the binder determines the rate of release of the active ingredient (col. 1, lines 19-21). The dosage may be a plurality of pellets having a dimension below about 2 mm, encompassing claims 25, 28, 35, 37 and 55. The pellets have a shape that is spherical (col. 7, lines 48-57) (instant claims 35, 37 and 40). The active ingredient comprises 0.0001 to 45% of the compositions (col. 10, lines 30-35). Various active agents may be used such as tonics (encompassing claim 93), anti-inflammatory, enzymes (instant claim 82) and anti-viral agents (col. 13 to col. 14, line 48). The pellets may comprise a matrix binder and a coating. These serve to control the release of the active. Binders include polymers such as starch and cellulose (col. 8, lines 53-68). Generally water is added to the compositions to aid in pelletisation (col. 11, lines 37-39), encompassing a water plasticizer. The matrix binder may comprise 50% of the particles

(col. 10, lines 22-25). Each pellet may comprise a homogeneous blend of the active, the weighing material and the matrix binder components (col. 10, lines 58-60). Magnesium stearate also may be added to the compositions (Example 3), encompassing claims 31 and 59.

Newton et al. differ from the instant claims insofar as it does not disclose the exact amounts of matrix material or encapsulant as recited in the instant claims and does not disclose a plasticized matrix comprising starch.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have formulated the pharmaceutical compositions of Loomis with the dimensions and the amounts disclosed by Newton motivated by the desire to use formulations known in the art for making pharmaceutical compositions.

It would have been obvious to have coated the actives before incorporating them into the matrix of Loomis et al. motivated by the desire to add an additional control release mechanism for the active agent as suggested by the teachings of Newton et al.

Newton et al. disclose the active may comprise 0.0001 to 45% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 1 to 85%, 5% to 50%, 3% to 50% and 5% to

20% of encapsulant (active agent) in the compositions of Loomis in view of Newton et al. consistent with the In re Peterson decision.

Loomis et al. disclose temperature ranges from 120 to 180 degrees C (col. 3, lines 3-8) similar to those disclosed by the instant specification up to 160 degrees C. Thus it is reasonable to conclude that the starches used by Loomis et al. are not "substantially dextrinized".

In regard to claims 38 and 64, the rate of release is controlled by the matrix material. The matrix materials of the instant claims comprise substantially the same components, a plasticized matrix comprising starch and a rate controlling agent as the compositions of the combined reference. Therefore one of ordinary skill in the art would reasonably conclude that the compositions would release the encapsulant in an aqueous or gastric juice environment in an amount of no more than from about 10% in about 1 hour to no less than about 90% in about 24 hours as recited by the instant claims.

Response to Arguments in Regard to Newton

Applicant argues that Newton does not teach or suggest a plasticized matrix material comprising starch which is not substantially destructured or dextrinized. Newton also discloses a higher density. Further Newton distinguishes the density of the instant claims from that of the reference.

The Examiner submits that the newly cited art cures the deficiencies of Newton. In regard to the density, the density is only recited in claims 34 and 61. In the case of

claims 34 and 61, Newton discloses that a conventional tablet or pellet has a density of 1000 to 1500 g/liter. Therefore it would have been obvious to have formulated the compositions of Loomis et al to have a density ranging from 1000 to 1500 g/liter because it is a density conventionally used for tablets and pellets. All other arguments appear to relate to Newton in view of Eden et al and are now moot.

3) Claims 42, 69, 70, 84 and 108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loomis et al. (US 5,852,114) in view of Newton et al. (US 4,938,967) as applied to claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 in further view of Tye et al. (US 5,308,636).

Loomis et al. in view of Newton et al. is discussed above and discloses native and granular starches used include wheat. The combination differs from the instant claims insofar as it does not disclose the wheat used as a starch source is durum wheat.

Tye et al. disclose gellable starch based systems. The compositions are useful in a wide variety of food and industrial application (Abstract). The starches include wheat sources such as semolina flour (see Example 5).

The reference differs from the instant claims insofar as it does not disclose the starches are used in a plasticized matrix formulated into discrete particles comprising an encapsulant.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used wheat durum (semolina flour) as the wheat starch in the compositions of the combined teachings of Loomis et al. in view of Newton et al. motivated by the desire to use a wheat starch suitable for making gellable compositions that can be ingested as disclosed by Tye et al.

4) Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 62, 64-67, 69, 73, 75, 79, 81-83, 85, 91, 92, 93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al. (US 4,938,967) in view of Fishman et al. (US 5,451,673).

Newton et al. disclose pharmaceutical compositions. The dosages are preferably capsules that contain one or more units. Selection of the binder determines the rate of release of the active ingredient (col. 1, lines 19-21). The dosage may be a plurality of pellets having a dimension below about 2 mm, encompassing claims 28, 35, 37, 40, 52, 55, 56, 62, 64, 67 and 73. The pellets have a shape that is spherical (col. 7, lines 48-57). The active ingredient comprises 0.0001 to 45% of the compositions (col. 10, lines 30-35). Various active agents may be used such as tonics (encompassing claim 93), anti-inflammatory, enzymes (instant claims 46, 75, 82 and 85) and anti-viral agents (col. 13 to col. 14, line 48). The pellets may comprise a matrix binder and a coating. These

serve to control the release of the active. Binders serve as carriers and include polymers such as starch and cellulose (col. 8, lines 53-68). Generally water is added to the compositions to aid in pelletisation (col. 11, lines 37-39), encompassing a water plasticizer. The matrix binder may comprise 50% of the particles (col. 10, lines 22-25). Each pellet may comprise a homogeneous blend of the active, the weighing material and the matrix binder components (col. 10, lines 58-60). Magnesium stearate also may be added to the compositions (Example 3), encompassing claims 31 and 59.

The reference differs from the instant claims insofar as it does not disclose the exact amounts of matrix material or encapsulant as recited in the instant claims and does not disclose the matrix is plasticized.

Fishman et al. disclose compositions comprising pectin and gelatinized starch. The films are useful as carriers such as tablets and encapsulation materials (col. 4, lines 33-36). The mixture of starch and pectin has high moduli and thus has many uses. Plasticizers are added to make the compositions less brittle (col. 4, lines 10-18). The compositions may be made by melt process by mixing the components together with sufficient water to allow the pectin and starch to melt at a temperature below their decomposition temperatures (col. 4, lines 53-57). The starch solution is prepared by mixing starch with water and heating it above the boiling point of water under pressure for a sufficient time to break down starch granules (col. 5, lines 1-4). Plasticizers are used in the compositions to make plasticized compositions. The compositions were plasticized at temperatures up to 200 degrees C (col. 8, lines 52-60).

The reference differs from the instant claims insofar as it does not disclose the size of the composition is up to 10 mm or that there is an encapsulant in the compositions.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used a heated plasticized starch matrix in the formulations of Newton et al. motivated by the desire to use a composition that is suitable for carriers and encapsulation materials as disclosed by Fishman et al.

It would have been obvious to have coated the actives before incorporating them into the matrix of Fishman et al. motivated by the desire to add an additional control release mechanism for the active agent as suggested by the teachings of Newton et al.

Newton et al. disclose the active may comprise 0.0001 to 45% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 1 to 85%, 5% to 50%, 3% to 50% and 5% to 20% of encapsulant (active agent) consistent with the In re Peterson decision.

In regards to the amounts recited in the instant claims such as the amount of matrix material, this is a result effective variable. The matrix material controls the release of the active and the active results in achieving the desired effect for the desired treatment. That being said, it would take no more than routine skill in the art to adjust

the amount of matrix binder in the pellets to achieve the desired active release profile including the amount of active released in an aqueous or gastric juice environment as recited in claims 38 and 65. Therefore it would have been obvious to one of ordinary skill in the art to have used about 60% to about 95% of the matrix material in the compositions of the combined teachings of Newton et al. in view of Fishman et al. motivated by the desire to release incorporated active materials at the desired rate.

Fishman et al. disclose temperature ranges up to 200 degrees C similar to those disclosed by the instant specification up to 160 degrees C. Thus it is reasonable to conclude that the starches used by Fishman et al. are not “substantially dextrinized” or “substantially destructured”.

5) Claims 25, 26, 28, 30, 31, 35, 37, 38-40, 46, 50, 52, 53, 55, 56, 58, 59, 62, 64-67, 69, 73, 75, 79, 81, 83, 91-93, 95-97, 101, 103, 105, 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desaga (DE 19503993) in view of Loomis et al. (US 5,852,114).

Desaga discloses compositions for supplying food ingredients or drug substances for improvement of glucose intolerance, insulin resistance or hyperlipidemia in obesity, etc. (page 1, paragraph 1). Actives include an omega-3 fatty acid with a content of at least 5% and an additional ingredient such as medium chain triglycerides with a content of at least 5% (page 1, paragraph 6). The fatty acid includes fish oil (page 1, paragraph 18) (instant claims 30, 31 and 93). The fatty acid is dispersed in a

plasticized starch matrix (page 1, paragraph 7) (instant claims 30, 31, 58 and 59). Starch products include cyclodextrins, native or modified starches. Various additives include vitamins, antioxidants and pharmacologically active substances. The compositions may be formulated into pellets with a diameter of 0.1 to 3 mm (page 2, paragraph 7) (instant claims 28, 35, 37, 40, 55, 62, 67 and 73).

The reference differs from the instant claims insofar as does not disclose the amount of matrix material in the compositions or that the starch is not substantially destructured or dextrinized.

Loomis et al. disclose biodegradable thermoplastic polymer blends comprising a first polymer and a second polymer. The polymers form a homogeneous blend (Abstract). The first polymer includes hydrophobic polymers and may comprise 20% to 80% by weight of the total compositions. Polymers also include polyvinyl pyrrolidone meeting instant claims 50 and 79. The second polymer ranges from about 10% to 70% by weight of the total composition and includes polyvinyl acetate copolymers, pectins, polysaccharides, starch cellulose and alginates. A starch component is also incorporated into the composition to impart further desirably physical properties and characteristics (col. 4, lines 63-67). The starch component includes native or granular starch, chemically modified starch, gelatinized starch and destructurized starch and combinations thereof, meeting the limitations of instant claims 108 and 109. Native and granular starch is selected from potatoes, rice, tapioca, corn, rye, oats, wheat and combination thereof (col. 8, lines 36-52). The starch component may comprise 5% to about 50%. Optional components, which may also be added to the compositions of the

present invention to impart further desirable physical properties and characteristics, may be selected from the group consisting of extenders; fillers; lubricants; mold-release agents; ultraviolet stabilizers; coloring agents; anti-oxidants (instant claims 46 and 75) and combinations thereof. Lubricants include stearates and lecithin (instant 30 and 31). Stabilizers include antimicrobial agents. Extenders include soybean proteins and gelatin, meeting the limitation of instant claims 52, 83, 69, 108 and 109. The compositions may be used for the controlled delivery of pharmaceuticals or agricultural chemicals. The compositions are formulated into granule, pellets or powders, meeting instant claims 28 and 55. The reference discloses water is removed and therefore water is present meeting the limitation of the plasticizer comprising water.

The reference differs from the instant claims insofar as it does not disclose the dimensions of the granules, pellets or powders; or the amount of optional components that may be added to the compositions.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have made the pellets of Desaga with the plasticized matrices comprising starch of Loomis et al. motivated by the desire to use a plasticized starch matrix suitable for delivering pharmaceuticals.

Loomis et al. disclose starch may comprise 5 to about 50% of the compositions. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness.

In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Therefore it would have been obvious to have used 40% or more of a matrix material consistent with the In re Peterson decision.

In regard to the starch not being substantially dextrinized or destructured, the starch may be a gelatinized starch which is disclosed as different from destructured starch, meeting the limitation of not substantially dextrinized or destructured.

Claims 25-31, 34, 35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69, 70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105 and 108-110 are rejected.

Claim 94 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612